DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

55154

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville MD 20852-1448

JAN - 3 2005

CBER-05-007

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Chris Rusnock
Heel Inc.
11600 Cochiti SE
Albuquerque, NM 87123

Dear Mr. Rusnock:

The Food and Drug Administration (FDA) has reviewed your website at Internet address http://www.heelusa.com and has determined that your Engystol injection solution, Engystol tablets, Engystol oral vials, Gripp-Heel injection solution, Gripp-Heel tablets, and Gripp-Heel oral vials are being promoted for conditions that cause the products to be drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) [21 USC 321(g)] and biologics, as defined in section 351(i) of the Public Health Service Act (PHS Act) [42 USC 262]. These products are considered drugs because the therapeutic claims shown on your website establish their intended use as drugs. We note that at least one component of these products is recognized in the Homeopathic Pharmacopeia of the United States (HPUS). Please be aware that a product's compliance with requirements of the HPUS does not establish that it has been shown by appropriate means to be safe, effective, and not misbranded for its intended use.

Background

Engystol injection solution, Engystol tablets, Engystol oral vials, Gripp-Heel injection solution, Gripp-Heel tablets, and Gripp-Heel oral vials are drugs under section 201(g) of the FD&C Act. According to your website, the products contain asclepias vincetoxicum, sulphur, aconitum napellus, eupatorium perfoliatum, phosphorus, and lachesis mutus. Each of these components is listed in the HPUS.

Examples of the claims observed on your website include:

- "Homeopathic flu vaccine";

- "...recommendation of use for Gripp-Heel and Engystol to prevent the occurrence of influenza;"
- "For low-risk patients, administer a mixed injection of Gripp-Heel (saline-based vial) and Engystol (saline-based vial) once a month...;"
- "For high-risk patients, administer a mixed injection of Gripp-Heel (saline-based vial) and Engystol (saline-based vial) once a week...;" and
- "If acute infection occurs, use Gripp-Heel and Engystol together (tablets)...."

Your website provides a mechanism for both licensed practitioners and consumers to purchase your products. Licensed practitioners can order products using the telephone and facsimile numbers listed on your website. Your consumer center states "Ordering the products of Heel/BHI from the comfort of home has never been easier. Simply choose a distributor by clicking on their logo." Your website provides a link to the website, at Internet address http://www.allnaturalusa.com, which lists the prices for your products and provides a mechanism for purchasing through the site. Specifically, the website checkout page offers shipping to addresses within the United States. Prices listed on the website are $14.99 for Engystol N 100 tabs, $29.99 for Engystol N 10 oral vials, $14.99 for Gripp-Heel 100 tabs, and $29.99 for Gripp-Heel 10 oral vials.

False or Misleading Information

The information on your website is false or misleading. For example, your website makes numerous effectiveness claims, but it lacks adequate descriptions of the risks, warnings, and contraindications of your products. Consequently, your products are misbranded under sections 502(a), 502(f)(1), and 201(n) of the FD&C Act, and are marketed in violation of sections 301(a) and 301(b) of such Act.

Failure to Require a Prescription

You have failed to require that your product be dispensed under a prescription from a duly licensed practitioner. Therefore, your product is misbranded under section 503(b)(1) of the FD&C Act, and is marketed in violation of sections 301(a), 301(b), and 301(k) of such Act.

For the reasons cited above, you should immediately discontinue any website offer to sell Engystol injection solution, Engystol tablets, Engystol oral vials, Gripp-Heel injection solution, Gripp-Heel tablets, and Gripp-Heel oral vials, and remove from your website all other promotional materials for products that contain the same or similar violative presentations.

This letter is not intended to be an all-inclusive review of your websites and products your firm may be marketing. It is your responsibility to ensure that all products marketed by your firm are in compliance with the FD&C and PHS Acts and their implementing regulations. You should take prompt action to correct the violations noted above. Failure to correct these violations promptly may result in regulatory action such as seizure and/or injunction without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the noted violations and to prevent their recurrence. If the

corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed.

Your response should be sent to the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality, HFM-600, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, Attention: Mary A. Malarkey, Director, Office of Compliance and Biologics Quality.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosure:
Internet website pages